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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,589	10/24/2003	Renzo Montanari	38068/GM/cb	7305

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MODIANO & ASSOCIATI  
Via Meravigli, 16  
Milano, 20123  
ITALY

EXAMINER

APANIUS, MICHAEL

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/691,589	<b>Applicant(s)</b> MONTANARI, RENZO	
	<b>Examiner</b> Michael Apanius	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3,6-9 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,6-9 and 12-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. This office action is in response to the request for reconsideration and amendment filed on 8/4/2006. The amendment is entered. The amendments to claims 3 and 6; the addition of new claims 12-16; and the cancellation of claims 4, 5, 10 and 11 are acknowledged. Currently, claims 3, 6-9 and 12-16 are pending.

#### *Claim Objections*

2. Claims 3, 6-9 and 12-16 are objected to because of the following informalities:
- a. At claim 3, line 7, it appears that "the the end of the test tube" should be --the end of the tube--.
  - b. At claim 3, line 7, it appears that the claim language should be modified to specifically name the previously recited element upon which the bottom is provided.
  - c. At claim 6, line 6, it appears that "the the end of the test tube" should be --the end of the tube--.
  - d. At claim 6, line 7, it appears that the claim language should be modified to specifically recite which of the previously recited elements is provided centrally with the bottom hollow.
  - e. At claim 12, line 1, it appears that "close" should be --closing--.
  - f. At claim 12, line 8, it appears that "and" should be deleted.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 3, lines 2-3, it is unclear if the "hollow needle arranged at an end of the tube" is a positive claim limitation because the hollow needle, as disclosed in the specification, is an element of the cylinder (1) and not the tube (5) which is claimed.

5. Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 12, line 8, it is unclear what is meant by "provided fully open prior to".

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Micheli (US 4,204,606) in view of Rosen et al. (US 6,562,300).

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8. Micheli discloses a tube (1) for collecting blood with a vacuum provided with a blood collection hollow needle (column 3, lines 58-61) arranged at an end of the tube and with a sealing stopper (12 in figure 1) comprising a front, external face thereof which comprises a cavity (14) that is formed on and opens externally to the stopper and a bottom which is provided with a piercing guiding point (a point just above 12 in figure 1) suitable for a hollow needle to pierce axially therein and further through said stopper for blood collection into the tube, and wherein said stopper further comprises: a peripheral region and a central region of said external face thereof, the central region being provided with an opening (16) for allowing needle access to said piecing guiding point provided in said cavity; an annular lip (17) that is formed monolithic with said stopper so as to protrude radially from said peripheral region over said external face, towards said central region thereof and up to and around said opening; and an annular groove.(around 14 in figure 1) that is formed under said annular lip and between said annular lip and said external face and surrounds said piercing guiding point, said groove being shaped so as to retain and contain any blood drop that is entrained out of the tube and through the stopper upon withdrawal of the needle from the stopper.

9. In regards to claim 7, the external cavity comprises an edge (around the cavity 14), said annular lip protruding radially inward from said edge so as to surround said central region opening and to form in said cavity the annular groove that surrounds said piercing guiding point.

10. In regards to claim 8, the opening is shaped so as to allow at least free passage of the needle covered by an elastic sheath.

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11. In regards to claim 9, the stopper has a collar (13) and a concentric cylindrical protrusion (just below 12 in figure 1) that is enclosed by said collar so as to provide a seat there between, the tube being engageable with a mouth part thereof in said seat for double, inner and outer sealing engagement (as in figure 2).

12. However, Micheli does not expressly disclose that the cavity has a spherical dome shape with a concavity that faces away from the end of the tube.

13. Rosen teaches a stopper with a concave surface (53) that faces away from the container for the purpose of assisting in resealing of the stopper (column 1, lines 59-65).

14. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have provided the cavity of Micheli with a spherical concave surface that faces away from the tube as taught by Rosen in order to allow the stopper to better reseal after removal of the needle.

15. Claims 12, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Micheli (US 4,204,606) in view of Burns (US 5,456,886). Micheli discloses the limitations of claims 12, 15 and 16 as noted above. However, Micheli does not expressly disclose a bottom hollow that forms a guide. Burns teaches a hollow (20) that forms a guide for the purpose of facilitating the insertion of the needle through the stopper (column 2, lines 10-13 and column 3, lines 14-31). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have provided the stopper of Micheli with a bottom hollow as taught by Burns in order to aid and direct the insertion of the needle through the stopper.

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16. Claims 6, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Micheli (US 4,204,606) as modified by Burns (US 5,456,886), as applied to claims 12, 15 and 16 above, and further in view of Rosen et al. (US 6,562,300). Micheli as modified by Burns discloses the claim limitations as noted above. However, Micheli as modified by Burns does not expressly disclose that the cavity has a spherical dome shape with a concavity that faces away from the end of the tube. Rosen teaches a stopper with a concave surface (53) that faces away from the container for the purpose of assisting in resealing of the stopper (column 1, lines 59-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have provided the cavity of Micheli as modified by Burns with a spherical concave surface that faces away from the tube as taught by Rosen in order to allow the stopper to better reseal after removal of the needle.

### ***Response to Arguments***

17. Applicant's arguments with respect to the previous prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

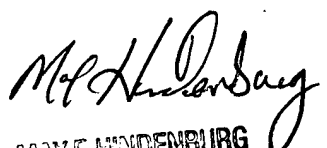
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

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19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA

  
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